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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/523,166

12/02/2005

Gerd Seibold

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03/03/2011

WORKMAN NYDEGGER  
1000 EAGLE GATE TOWER,  
60 EAST SOUTH TEMPLE  
SALT LAKE CITY, UT 84111

EXAMINER

BLATT, ERIC D

ART UNIT

PAPER NUMBER

3734

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/523,166	<b>Applicant(s)</b> SEIBOLD ET AL.	
	<b>Examiner</b> Eric Blatt	<b>Art Unit</b> 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 25-30 and 32-40 is/are pending in the application.
- 4a) Of the above claim(s) 25-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30 and 32-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8-3-2010; 9-16-2010; 2-9-2011</u> .                           | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

Claims 25-30 and 32-40 are pending. Claims 25-29 are withdrawn. Claims 30 and 32-40 are rejected herein.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 30, 32-34 and 36-40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24-61 of copending Application No. 11/117556. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed structure is substantially identical with the exception that the present application does not recite a delivery sheath configured to receive the closure structure. Such delivery sheaths were well known in the art, and it would have been obvious to one of ordinary skill in the art to provide the presently claimed apparatus with a delivery sheath in order allow delivery of the device to the puncture site.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action

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has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10-25-2010 has been entered.

### ***Claim Objections***

Claim 36 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 36 recites that the second disk is movably coupled to the first disk, but claim 30, from which claim 36 depends, includes a recitation that the second disk is moveably connected to the wire frame of the first disk. Claim 30 therefore already requires that the second disk is movably coupled to the first disk.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 30, 32-38, 40-54, 56-58, 60 and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Stevens et al. US (US 5,855,614).

Stevens discloses an apparatus for sealing a subcutaneous puncture site (Figures 24A-26B, Col. 22 Line 66 to Col. 25 Line 36) comprising a delivery sheath 24

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that receives an occlusion element 130D wherein the occlusion element comprises a first disk 244 comprising a membrane made of a material that is flexible and fluid impermeable and a self expanding wire frame 246, 260 supporting the membrane such that the wire frame is foldable into a first collapsed configuration when the disk is folded within the delivery sheath and an expanded configuration once outside of the delivery sheath, and a second disk (disclosed as attached to struts 252). The second disk is movably connected to the wire frame of the first disk prior to and throughout deployment so as to advance together as an integral unit through the puncture tract. The second disk is configured for placement within the puncture tract to securely engage the tissue of the puncture tract and when secured within a puncture tract, the second disk is capable of exerting a lateral force on the surrounding tissue of the puncture tract and exerting a longitudinal force on the first disk when it is unfolded in order to urge the first disk against the puncture site to facilitate sealing of the puncture site. The second disk comprises a self-expanding wire frame 246, 252 that is foldable and self-expanding as claimed. The first disk and the second disk are separated by a first distance in the first configuration within the delivery sheath (Figure 25A) and a second, smaller distance in the second deployed configuration (Figure 24B).

The occlusion element is configured to be releasably engaged to the interior vessel surface allowing the apparatus to be repositioned. (Col. 24, Lines 2-5) There is a stop feature 261 that prevents accidental disengagement of the first and second disk. (Figure 25A) The first disk is configured to engage tissue via barbs. (Figure 24B) There

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is a minimally invasive delivery element 22 configured to deliver the first disk and the second disk.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens et al. (US 5,855,614) in view of Yang (US 6,596,013).

Stevens discloses all elements of claim 35 as previously discussed except for the first disk being attached to a nut and the second disk being attached to a bolt such that the nut is configured to be moveably coupled to the bolt. Stevens discloses multiple embodiments of connection means between the first and second disks and in Figures 10-12, shows an embodiment wherein the hubs of the disks are movable relative to one another. This advantageously allows the first disk hub to be spaced distally from the second disk hub to allow the first disk to be more easily maneuvered, and after the desired position has been obtained, the hubs may be moved toward one another to provide a close engagement on opposite sides of the tissue puncture. (See Figures 10-18) Yang teaches a connection means between hubs of a two-disk sealing member wherein the first disk is attached to a nut and the second disk is attached to a bolt such that the nut is configured to be moveably coupled to the bolt. (Figure 11) It would have

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been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus shown in Figures 24A-26B of Stevens by attaching the first disk to a nut and the second disk to a bolt such that the nut is configured to be moveably coupled to the bolt as shown in Yang in order to allow the hub of the first disk to extend a length from the hub of the second disk such that the first disk may be more easily maneuvered and positioned on the distal side of the puncture.

Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens et al. (US 5,855,614) in view of Shaw (US 6,080,182).

Stevens teaches all elements of claim 39 as previously discussed except for at least one delivery element being constrained to translate a maximum distal depth. Shaw discloses a related system having at least one delivery element constrained to translate a maximum distal depth. (Figure 36, Column 17, Lines 16-30) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Stevens by providing a delivery element constrained to translate a maximum distal depth in order to provide a mechanical indication to a physician that the sealing device has been pushed out of the delivery catheter as taught by Shaw.

### ***Response to Arguments***

Applicant's arguments with respect to claims 30 and 32-40 have been considered but are moot in view of the new ground(s) of rejection.



***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is 571-272-9735.

The examiner can normally be reached on Monday-Friday, 9:00 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on 571-272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. B./  
Examiner, Art Unit 3734

/Gary Jackson/  
Supervisory Patent Examiner, Art Unit 3734  
February 19, 2011